

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

_____)	
SECURITIES AND EXCHANGE COMMISSION,)	
)	
Plaintiff,)	
)	
v.)	Case No. 1:16-cv-10607- NMG
)	
DAVID JOHNSTON)	
)	
Defendant.)	
_____)	

**PLAINTIFF’S MEMORANDUM IN OPPOSITION TO DEFENDANT DAVID
JOHNSTON’S MOTION FOR JUDGMENT AS A MATTER OF LAW**

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INTRODUCTION

David Johnston's Motion for Judgment as a Matter of Law ("Motion") contends that the record does not contain a legally sufficient evidentiary basis for a reasonable jury to find him liable for securities fraud because this is an "omissions case" in which the company did not have a general duty to disclose "any and all" of its interactions with the FDA. This argument completely ignores the evidence that the Commission has presented as the basis for Johnston's liability. The record before the jury shows that Johnston along with others members of Aveo's executive management team engaged in a scheme to defraud investors by selectively disclosing only part of the FDA's overall survival concerns, intentionally holding back the FDA's recommendation to conduct a whole new phase 3 clinical trial that, when disclosed by the FDA on April 30, 2013, caused Aveo's stock to drop by 31 percent and its market value to plummet by over \$100 million. As set forth below, there is more than enough evidence in the record for a reasonable jury to conclude that Johnston led this scheme to defraud and made his own misleading statements of fact in support of that scheme to deceive Aveo's investors. The Court should deny his motion and send this case to the jury.

STANDARD

When reviewing a motion for judgment as a matter of law, "the court should review all of the evidence in the record." *Reeves v. Sanderson Plumbing Products, Inc.*, 530 U.S. 133, 150 (2000). In reviewing the evidence, "the court must draw all reasonable inferences in favor of the non-moving party, and it may not make credibility determinations or weigh the evidence." *Id.* And, "it must disregard all evidence favorable to the moving party that the jury is not required to believe." *Id.* at 151.

ARGUMENT

I. A Reasonable Jury Could Find Johnston Led a Scheme to Defraud Investors

Just as Johnston did in his summary judgment motion, he continues to mischaracterize the Commission's case as "an omissions case." *See* Motion, p.2. It's not just that. The Commission alleged a scheme to defraud. Perhaps because he has no answer to these allegations (and now record evidence), Johnston deliberately ignores all of the evidence showing that he and his communications team employed a deceptive device that Aveo and its officers used as part of a scheme to defraud investors.

Exchange Rule 10b-5(a) and Securities Act Section 17(a)(1) make it unlawful to employ any device, scheme or artifice to defraud. 15 U.S.C. §77q; 17 C.F.R. §240.10b5(a). Scheme liability arises where defendants "employ a deceptive device for the purpose of defrauding investors." *SEC v. Esposito*, 260 F. Supp. 3d 79, 91 (D. Mass. 2017). This is what Johnston and Aveo did. As David Johnston admitted on the stand and as shown in Trial Exhibit 92 (August 2, 2012 Press Release), the company used the August 2, 2012 press release's disclosure of the FDA's overall survival concerns as a means to explain the potential delay of its NDA filing from one quarter to the next. Harper Decl., Ex. B, Trial Tr., 4-153:2-154:6. Johnson also admitted that knew that this disclosure of FDA concern would raise questions from analysts about whether the agency requested additional studies. *Id.*, Ex. B, Trial Tr., 4-162:9-19. Johnston further testified that he and his team created a Question and Answer script designed to tell only half the story, concealing any reference to what they knew – that the FDA's concerns were so severe that the agency had recommended that Aveo conduct a whole new clinical trial. *Id.*, Ex. B, 4-159:15-162:18; *id.* Ex. M, Trial Ex. 75 (Aveo 2Q2012 Q&A), p. 3 ("IF PUSHED...details on discussions with FDA). This script was then provided to Aveo's CMO, Dr. Slichenmyer, for

him to use when answering analyst questions after the press release issued. *Id.*, Ex. B, Trial Tr., 4-13:6-4-14:7 Dr. Slichenmyer admitted that he used that script on the conference call to give his misleading answers that he could not “speculate” when he actually already knew of the FDA’s recommendation to conduct another clinical trial. *Id.*, Ex. B, Trial Tr., 4-14:10 to 4-21:1; *id.*, Ex. N, Trial Ex. 76 (Reuters Conference Call Transcript). Johnston sat in on the call as Dr. Slichenmyer gave the misleading answers to analyst questions, following the plan to hide the material fact that the FDA had already recommended a second clinical trial. *Id.*, Ex. B, Trial Tr., 4-163:17 to 4-164:20. Viewing these facts in the light most favorable to the Commission, a reasonable jury could find that Johnston was part of a scheme to defraud investors by orchestrating the concealment of the FDA’s recommendation to conduct a second trial during analyst questioning about the FDA’s overall survival concerns.

II. A Reasonable Jury Could Find Johnston Made Affirmative Selective Disclosures that Withheld a Material Fact that He Had a Duty to Disclose

Wishing the facts were different, Johnston clings to cases standing for the proposition that the securities laws do not create a general duty for publicly traded pharmaceutical companies to disclose material information concerning regulatory back and forth. *See* Motion, p. 2-4 (citing, e.g., *Fire & Police Pension Ass’n of Colorado v. Abiomed, Inc.*, 778 F.3d 228 (1st Cir. 2015) and *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 542 (S.D.N.Y. 2015)). These cases, however, are inapposite here because the record evidence is that Johnston and Aveo deliberately misled investors by selectively disclosing only part of the FDA’s stated concern about overall survival, and withholding the FDA’s official recommendation to conduct a second trial to resolve that specific survival concern. As the Court noted in denying Johnston’s motion for summary judgment, “[a]ny voluntary disclosure of information that a reasonable investor would consider material must be ‘complete and accurate’ and a company must disclose facts that are necessary

so that ‘what was revealed would not be so incomplete as to mislead.’ *Tutor Perini Corp. v. Banc of Am. Sec., LLC*, 842 F.3d 71, 88 (1st Cir. 2016).” ECF No. 133 (Memo & Order).

And, here, there is sufficient evidence for a reasonable jury to find that, as part of the scheme, David Johnston made selective disclosures of the FDA’s survival concerns that gave rise to a duty to disclose the material recommendation to conduct a whole new clinical trial. When a company or person makes a partial disclosure, but omits a fact that changes the meaning of what was disclosed, a duty to disclose arises. *See In re Boston Tech., Inc. Sec. Litig.*, 8 F. Supp. 2d 43, 53 (D. Mass. 1998). Once a company or its officers make a voluntary disclosure that a reasonable investor would consider material, they have a duty to make that disclosure complete and accurate. *See Rosenbaum Capital LLC v. Boston Commc’ns Group, Inc.*, 445 F. Supp. 2d 170, 175-176 (D. Mass. 2006); *Bachman v. Polaroid Corp.*, 910 F.2d 10, 16 (1st Cir. 1990) (“even a voluntary disclosure of information that a reasonable investor would consider material must be ‘complete and accurate’”) (citation omitted). That is what Johnston and Aveo did here. At trial, David Johnston admitted that on August 2, 2012, he led the company’s decision to disclose the FDA’s concerns about the overall survival data. Declaration of Richard Harper (hereinafter, Harper Decl.), Ex. A, Trial Transcript, 5-37:7-18. He also admitted he believed these concerns were material because he expected the market to react “pretty negatively” to this information, which turned out to be correct when the stock dropped by 27 percent on August 2, 2012. *Id.*, 5-40:11-20. He also admitted that he deliberately withheld the FDA’s recommendation, made at the same preNDA meeting, to conduct another trial to resolve those concerns. Harper Decl., Ex. B, Trial Tr., 4-167:7-11. Further, Johnston made Aveo’s selective disclosure when he authorized the filing of the August 2, 2012 press release and filed it with the Commission on a Form 8-K. Harper Decl, Ex. C, Trial Ex. 92 (Form 8-K Filing Aug. 2, 2012

Press Release); *Id.*, Ex. B, Trial Tr., 4-151:6 to 20. This press release disclosed the FDA's concern about overall survival, but, as Johnston planned, omitted any mention of the FDA's recommendation to conduct a second clinical trial. *Id.* Ex. C, Trial Ex. 92, p.7; *Id.*, Ex. B, Trial Tr., 4-152:24 to 4-156:20. He continued to make these selective disclosures in four of Aveo's later SEC filings and at each of the four investor conferences he attended in 2012 and 2013, where he appeared and described the FDA's overall survival concerns, while continuing to withhold the FDA's recommendation to conduct a second clinical trial. See, *infra*, Section III, pp. 7-11 (detailing misleading factual statements in public filings and investor conferences).

Furthermore, when viewing the record in the light most favorable to the Commission, there is ample evidence for a reasonable jury to find that the FDA recommendation that Johnston withheld was a material fact that warranted disclosure. Both Johnston and Slichenmyer admitted that the FDA's recommendation created a possibility that the FDA might not approve Tivo without the second trial. Harper Decl, Ex. B, Trial Tr., 4-132:16-25 (Johnston admitting risk of non-approval); 4-23:7-23 & 4-27:24 (Slichenmyer admitting pre-approval risk open through the end of FDA review). As the court explained in its memorandum and order denying Johnston's motion for summary judgment, "where information creates a possibility that an event will later occur, the materiality of the information depends on a balancing of the indicated probability that an event will occur and the 'anticipated magnitude of the event in light of the totality of the company activity.'" ECF 133 (Memo & Order), p. 11 (quoting *In re Boston Sci. Corp. Sec. Litig.*, 686 F.3d 21, 27 (1st Cir. 2012)).

With regard to the first part of the balancing, the indicated probability of the event, there is ample evidence for a reasonable jury to conclude that the FDA's recommendation of a second trial created a high risk of non-approval. Indeed, Aveo's Chief Medical Officer, Dr. William

Slichenmyer, testified that he told Aveo's Executive Committee exactly that on the evening after the pre-NDA meeting. After the preNDA meeting, Dr. Slichenmyer created a PowerPoint slideshow, which he delivered to the Aveo Executive Committee, including Johnston. Harper Decl., Ex. E, 3-189:17 to 3-199:13. And, as part of that presentation, he told them that failing to do the recommended second trial would lead to a "high risk" of non-approval. *Id.*, Ex. E, 3-189:17 to 3-199:13; *id.*, Ex. D, Trial Ex. 63, p. 6 of 7. Johnston saw this presentation and "understood" the "high risk." *Id.*, Ex. B, Trial Tr., 4-127:15-20. This high risk probability is supported by all of the testimony and documents showing (i) that the FDA told Aveo that it was in the company's "best interest to conduct another randomized trial"; *Id.*, Ex. B, Trial Tr., 4-138:10 to 141:4-21; *Id.*, Ex. D, Trial Ex. 67 (May 30, 2012 Aveo Board Presentation), p. 5 ("Additional FDA Feedback"); (ii) the weeks of work that Aveo and Astellas did to design and propose a second clinical trial to the FDA, *id.*, Ex. E, Trial Tr., 3-210:7 to 3-217:15 (Slichenmyer describing work done); *id.* Ex. F, Trial Ex. 44 (Joint Steering Committee Meeting Minutes); (iii) Aveo's board approval of a new clinical trial expected to cost \$83 million and take over three years to complete, *id.*, Ex. E, Trial Tr. 3-217:16 to 3-3-219:14, *id.*, Ex. B, 4-3:25 4-8:22 (Slichenmyer describing board approval process); *id.*, Ex. G, Trial Ex. 67 (June 26, 2012 Board Presentation), pp. 5 & 7 (detailing length of proposed trial and cost); (iv) Aveo's vigorous, and ultimately unsuccessful, regulatory strategy to get an agreement from the FDA that the trial could be done after approval, *id.*, Ex. B, Trial Tr., 4-8:23 to 4-11:11 (Slichenmyer describing failure to obtain agreement); and (v) the views of Astellas that the FDA's feedback to the Type A meeting request indicated that the FDA might require the trial prior to approval. *Id.*, Ex. E, Trial Tr., 3-45:25 to 3-47:18 (Eck); *Id.*, Ex. H, Trial Ex. 51 (Eck email stating Astellas objection to Aveo's cancellation of Type A meeting); *id.*, Ex. E, Trial Tr., 3-103:15 to 3-107:3

(Fitzsimmons).

With regard to the anticipated magnitude of the event, there is ample evidence from which a reasonable juror could find that a pre-approval requirement would have been a disaster for Aveo. The company had no other drug so close to market. Indeed, the company's 2011 and 2012 Forms 10-K, which Johnston certified, reported that the company was "dependent on the success of its lead drug candidate, tivozanib." Harper Decl., Ex. I, Trial Ex. 1 (Aveo's 2011 Form 10-K), pp. 51-52 of 215; *id.*, Ex. J, Trial Ex. 4 (Aveo's 2012 Form 10-K), pp. 42-43 of 275. Johnston admitted this fact at trial. *Id.*, Ex. B, Trial Tr., 4-114:17 to 4-115:5. Further, the Commission's financial economist found that once the FDA's recommendation was disclosed on April 30, 2013, that recommendation (the same recommendation made by the FDA nearly a year earlier) caused Aveo's stock price to decline by \$2.32 or 31 percent, *Id.*, Ex. K, Trial Tr., 6-45:9-24; 6-49:25 to 6-50:11, and Johnston's own expert calculated that drop as causing Aveo to lose over \$100 million in market value. *Id.*, Ex. L, Trial Tr., 7-183:12 to 7-184:1. Viewing this evidence in the light most favorable to the SEC, there is no doubt a reasonable juror could conclude that the non-approval of Tivo would have been devastating to Aveo.

With this record evidence, the jury should now decide whether David Johnston selectively withheld a material fact from Aveo's investors that he had a duty to disclose. *See* ECF No. 133 (Memo & Order), p.10 (noting materiality of an omission is a question generally left to the jury.")

III. A Reasonable Jury Could Find that Johnston Made Misleading Statements of Fact

Johnston contends that the evidentiary record shows that he made statements of "opinion," rather than misleading statements of fact. This argument displays, at best, a willful blindness to the evidentiary record. When viewed in the light most favorable to the Commission,

there are ample facts from which the jury could find that Johnston made misleading statements of fact.

For example, Johnston authorized the publication of the August 2, 2012 Press Release and its filing with the Commission on Form 8-K. Harper Decl., Ex. C, Trial Ex. 92 (Form 8-K Filing Aug. 2, 2012 Press Release); *Id.*, Ex. B, Trial Tr., 4-151:6 to 20. As David Johnston has admitted, the Regulatory Update stated the facts of the FDA's overall survival concern, but, at his direction, withheld the fact of the FDA's simultaneous recommendation to conduct a second trial. *Id.*, Ex. C, Trial Ex. 92, p.7; *Id.*, Ex. B, Trial Tr., 4-152:24 to 4-156:20. Neither of those expressions of fact was couched as, nor expressed as, "opinion" or "belief."

Then there are Aveo's periodic Commission filings that David Johnston certified for filing with the Commission. These start with the Form 10-Q for the period ending June 30, 2012, which Johnston signed and certified for filing with the Commission on August 7, 2012. Harper Decl., Ex. O, Trial Ex. 5 (Aveo Form 10-Q for period ending June 30, 2012), p. 82 of 134 (Johnston Certification); *Id.*, Ex. B, Trial Tr., 4-111:23-4-112:9. Within that Form 10-Q, Aveo states: "The FDA has expressed concern regarding the overall survival trend in the TIVO-1 trial and has said that it will review these findings at the time of the NDA filing as well as during the review of the NDA." *Id.*, Ex. O, Trial Ex. 5, p. 51 of 134. This statement of fact also intentionally said nothing about the FDA's recommendation to conduct a second clinical trial. After this filing, Johnston signed and certified two more periodic filings containing similar misleading statements of fact about the FDA's expression of concern regarding overall survival, again leaving out the FDA's recommendation to conduct a second clinical trial. See *id.*, Ex. P, Trial Ex. 10 (Form 10-Q for period ending Sept. 30, 2012), p.45 of 124 ("The FDA has expressed concern regarding the overall survival trend in the TIVO-1 trial and has said that it

will review these findings at the time of the NDA filing as well as during the review of the NDA.”); *id.*, Ex. Q, Trial Ex. 4 (Form 10-K for the year-ended Dec. 31, 2012), p.43 of 275 (“The FDA has expressed concern regarding the overall survival trend in the TIVO-1 trial and has said that these findings will be a subject of review during the NDA process.”); *id.*, Ex B, Trial Tr., 4-108:4 to 4-112:9 (admitting to certifying these Commission filings) Also, in January 2013, Johnston signed another Form 8-K issuing the company’s revised risk factor disclosures, which, yet again, made the same misleading statement about the FDA’s overall survival concern. *Id.*, Ex. R, Trial Ex. 103 (Form 8-K dated Jan. 16, 2013), p.7 of 30 (“The FDA has expressed concern regarding the overall survival trend in the TIVO-1 trial and has said that it will review these findings at the time of the NDA filing as well as during the review of the NDA.”); *id.*, Ex. B, Trial Tr., 4-113:15 to 33 (admitting to signing Form 8-K on behalf of Aveo’s filing).

In addition, David Johnston made similar misleading statements of fact at four investor conferences. Starting on August 16, 2012, at the Canaccord Genuity Global Growth Conference, Johnston described the facts of the FDA preNDA meeting as follows:

When we met with the FDA in our pre-NDA meeting, this [overall survival detriment] caught their eye, and it’s –properly, it’s the FDA’s job to present safe and effective drugs to the U.S. population. And even though overall survival in this therapy is not an approvable endpoint, this is – the overall survival trend is moving in a different direction than PFS, and they expressed some concern and they would like an explanation. So along those lines, we are doing a lot of analyses to help address their concern, and we expect to do so as we file our NDA later this quarter.

Harper Decl, Ex. S, Trial Ex. 6, p. 3 of 6. This statement of fact intentionally concealed the FDA’s recommendation to conduct a second clinical trial. And, at trial, David Johnston admitted that, at the time he made these statements of fact at the investor conference, he knew, but did not disclose, that Aveo had already planned, budgeted and started designing the recommended second clinical trial, Tivo-2. *Id.*, Ex. B, Trial Tr., 4-180:5-14.

On September 10, 2012, at the Morgan Stanley Global Health Conference, Johnston explained the FDA's concern about overall survival by saying:

Now that led the FDA to then say, this is something we need you to explain, and we expect to see it in your NDA submission and we expect to see from overall survival data et cetera. So that's what we're up with the FDA on now. And we've been having conversations with them throughout the summer. And as of right now, we are still on target to submit the NDA by the end of Q3 depending on the overall survival analysis, it may slip into the first part of Q4.

Harper Decl, Ex. T, Trial Ex. 99, p.2 of 9. This statement of fact, again, omitted the FDA's recommendation to conduct a second clinical trial as well as all of Aveo's efforts to design, budget and propose the new Tivo-2 trial to the FDA. At trial, Johnston admitted that he did not mention Tivo-2. *Id.*, Ex. B, Trial Tr., 4-203:2-17.

On September 20, 2012, at the UBS Global Life Sciences Conference, Johnston gave a similarly misleading description of the FDA's overall survival concern saying:

And that was a statistic that was noted at our pre-NDA meeting with the FDA. They were rightly concerned with the fact that the overall survival trends were going in a differed direction of PFS. Now at that time, they didn't see any backup analysis. There was no explanation. They simply said, we need to understand this. And we think that is the right thing. It's the FDA's job to provide safe and effective drugs.

Harper Decl, Ex. U, Trial Ex. 101, p.3 of 5. Here, yet again, Johnston provided a factual explanation of the FDA's concern, but left out the material fact that the FDA had recommended that Aveo conduct a whole new clinical trial, which the company had already designed, budgeted and proposed to the FDA. *Id.*, Ex. B, Trial Tr., 4-206:8 to 4-207:15 (Johnston admitting he did not disclose submission of proposed trial to FDA).

And, at the RBC Capital Markets Global Healthcare Conference in February 2013, securities analyst Adnan Butt asked Johnston: "Have you – either your partner or the FDA discussed any further trials in kidney cancer so far?" Harper Decl., Ex. V, Trial Ex. 16, p. 7.

Johnston answered, “We have not had any formal discussions, no.” *Id.* As Johnston admitted at trial, when he gave this misleading answer, he knew that Aveo had already designed and proposed the new clinical trial to the FDA in a formal Type A meeting request. *Id.*, Ex. B, Trial Tr., 4-212:3-213:8.

As demonstrated by the record, when viewed in the light most favorable to the Commission, there is more than enough evidence for the jury to find that Johnston made misleading statements of fact that were not opinion.

IV. A Reasonable Jury Could Find Johnston Acted with Scienter when He Misled Investors

There is also more than enough evidence in the record for a reasonable jury to find that Johnston acted with scienter when he led Aveo’s communications strategy to never disclose the FDA’s recommendation unless it became a requirement.

First, Johnston admitted he reviewed and understood Dr. Slichenmyer’s presentation on May 11, 2012 (the one delivered on the same day as the preNDA meeting) that the FDA’s concerns that included the recommendation for a new trial created a “high risk” of non-approval if Aveo submitted an NDA for Tivo without doing the recommended study. *Id.*, Ex. B, Trial Tr., 4-127:14-20

Second, Johnston admitted that when the company disclosed the FDA’s overall survival concern on August 2, 2012, he knew that it would cause investment analysts to want to know if the FDA had recommended any additional clinical trials. *Id.*, 4-160:2-14; 4-162:16-19.

Third, with the knowledge of the high risk the FDA’s recommendation posed to approval and the obvious interest of market securities analysts, Johnston then led his communications team in a deliberate plan to withhold any mention of the recommendation on the earnings conference call that followed the August 2, 2012 press release. *Id.*, 4-167:7-11

Fourth, David Johnston sat in on the August 2, 2012 conference call and listened as Aveo's CMO, Dr. Slichenmyer, followed the script and delivered the misleading answers to the questions from analysts eager to understand the full extent of what the FDA had asked Aveo to do to remedy the FDA's concerns. These questions included a point-blank question from analyst Salveen Richter about whether the FDA had "pushed" Aveo on doing some additional studies. *Id.*, Trial Tr., 4-163:17-18; 4-164:10-12, 18-20; 4-167:18-168:6; *Id.*, Ex. N, Trial Ex. 76 (Transcript of Aug. 2, 2012 conference call).

In the face of this powerful evidence of willful intent to mislead investors, Johnston advances three flimsy excuses, which do nothing to erode the power of this evidence. Furthermore, Johnston's arguments really just dispute this evidence, which is not a basis to grant a Rule 50 motion. As the Court is well aware, the sole question posed by such a motion is whether, in the light most favorable to the Commission, there is legally sufficient evidence for a reasonable jury to find that Johnston acted with scienter. As set forth above, there is.

The first of Johnston's scienter arguments is that, because there is insufficient evidence for the jury to find he had a duty to disclose, he therefore could not have acted with scienter when he intentionally carried out the plan to withhold the recommendation from investors. As the Commission set forth above in Section II, there is more than sufficient evidence for a reasonable jury to find that David Johnston affirmatively and deliberately disclosed only part of the FDA's survival concerns, thus giving rise to a duty to disclose the recommendation of a second trial.

Second, Johnston claims that his participation in Aveo's boilerplate risk factor disclosures in Aveo's SEC filings somehow excuses him from deliberately creating a plan to withhold the FDA recommendation from investors. The ridiculousness of this argument is

shown by what Johnston actually did. If it were true that Johnston believed that the company's risk-factor disclosures had already informed investors of the risk posed by the FDA's actual recommendation, he would have not created an internal plan to withhold that fact from investors on the August 2, 2012 conference call. As the Court noted in denying Johnston's motion for summary judgment, "[a] reasonable factfinder could find that the disclosures made were insufficient to 'weaken the inference of scienter,' *City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp.*, 632 F.3d 751, 760 (1st Cir. 2011), and that the public-facing statements made by Johnston and Aveo diverged significantly from internal discussions such that a jury could infer an intent to deceive. *Greebel*, 194 F.3d at 196." ECF No. 133 (Memo & Order), pp.16-17.

Third, Johnston cites evidence that he followed Aveo's processes for corporate disclosure process as a basis to find that he lacked scienter. But Johnston's participation in this process cannot insulate him from liability. First, in the process itself, Astellas told Johnston that the FDA recommendation should be disclosed. In August 2012, Johnston received an email from Astellas's corporate communications group that told Aveo that Astellas thought "it is fair to note that an additional study will also be conducted and is under discussion with the FDA," Harper Decl., Ex. W, Trial Ex. 94 (Kataoka email); Trial Tr., 6-9:5 to 6-12:20. Second, the analyst questions during the August 2, 2012 investor conference call should have prompted additional review and internal questioning of the chosen course of action. Third, Johnston admitted that he did not wait to consider the views of everyone in this process. He admitted on the stand that he did not typically wait to ensure he received feedback from Aveo board members prior to making company disclosures, *Id.*, Ex. A, Trial Tr. 5-224:10 to 5-226:6. And, fourth, there is evidence that, during the process, Johnston was not entirely honest in his depiction of the risk at stake,

including intentionally downplaying the risk of the FDA’s recommendation in making management representations to JP Morgan’s underwriting counsel, Pat O’Brien, in January 2013. *Id.*, Ex. A, Trial Tr., 5-145:24 to 5-149:22.

In sum, there is more than enough evidence from which a reasonable jury could find that Johnston acted with scienter when he carried out Aveo’s plan to deliberately withhold from investors the FDA’s recommendation to conduct another clinical trial. Furthermore, as the First Circuit has pointed out, state of mind – like materiality – is typically a question left for the jury. *SEC v Ficken*, 546 F.2d 45, 51 (1st. Cir. 2008); *see also SEC v. EagleEye Asset Management, LLC*, 975 F. Supp. 2d 151, 160-61 (D. Mass. 2013) (“[e]ncroaching upon the province of juries to decide questions of fact, such as the defendant’s state of mind, violates not only the constitutional rights of the parties in the suit, but also the constitutional rights of the jurors themselves.”). This is especially true where, as here, there is record evidence showing a divergence between Aveo’s internal assessment of a “high risk” of nonapproval posed by the recommendation to do another trial and the company’s outward-facing statements on the FDA’s concerns about overall survival, which Johnston ensured would omit that recommendation. *Greebel v. FTP Software, Inc.*, 194 F.3d 185, 196 (1st Cir. 1999) (identifying “divergence between internal reports and external statements on same subject” as relevant evidence to show scienter).¹

V. A Reasonable Jury Could Find Johnston Falsely Certified Aveo’s Periodic Filings

Rule 13a-14 of the Exchange Act required Johnston, as a CFO of a public company, to issue a personal certification indicating that he reviewed Aveo’s Commission filings made

¹ Johnston argues that the same evidence that indicates that he lacked scienter also shows that he acted with due care. Motion, p.20-21. The Commission responds that the same evidence detailed in the text above providing a sufficient evidence for a reasonable jury to conclude that Johnston acted with scienter also provides a basis for a reasonable jury to conclude that he acted without due care in orchestrating the withholding of the FDA’s recommendation from investors.

pursuant to Section 13(a) of the Exchange Act (the Forms 10-Q and 10-K) and that, based on his knowledge, the reports did not contain any materially misleading statements. 17 C.F.R. §240.13a-14 (2002). Johnston made those certifications for Aveo's Forms 10-Q for the periods ending June 30, 2012 and September 30, 2012, and its Form 10-K for the year ended December 31, 2013. Harper Decl., Ex. B, Trial Tr., 4-110:18-23; 4-111:1-9, 12-19; 4-111:23-112:5. As set forth above, there is a legally sufficient evidentiary basis for a reasonable jury to find that when Johnston certified these forms he knowingly or negligently failed to disclose a material fact – the FDA's recommendation to conduct a second clinical study – and, by extension, falsely certified Aveo's public filings.

CONCLUSION

Based on the foregoing, the Commission respectfully submits that there is a legally sufficient evidentiary basis for a reasonable jury to conclude that David Johnston made voluntary selective disclosures of the FDA's survival concerns that gave rise to a duty to disclose the FDA's recommendation to conduct a second clinical trial for Tivo. There is also legally sufficient evidence for a reasonable jury to conclude that Johnston knowingly and negligently misled investors by withholding that official FDA recommendation from disclosure as part of a corporate communications scheme undertaken with others in the company and as part of his own misleading statements to investors. The Court should submit this case to the jury.

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DATED: November 19, 2018

CERTIFICATE OF SERVICE

I, Richard M. Harper II, hereby certify that this document was filed on this date through the ECF system and will be sent to the registered participants as identified on the Notice of Electronic Filing (NEF) as of the date of this filing.

/s/ Richard M. Harper II

DATED: November 19, 2018